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## (54) Improvements in or relating to surgical devices

(57) Apparatus for intubation of the cervix, especially for the implantation of a fertilised ovum, comprises a hub connected to a flexible catheter and a sheath surrounding said catheter, said sheath being more rigid than said catheter and having an enlarged grip portion adapted to be gripped by an

operator at its proximal end, said sheath being slidable from a first position in which the distal end of said catheter terminates approximately level with the distal end of said sheath to a second position in which said grip portion is abutting said hub and said catheter projects beyond the distal end of said sheath by a distance not less than the intended depth of intubation into the cervical canal.

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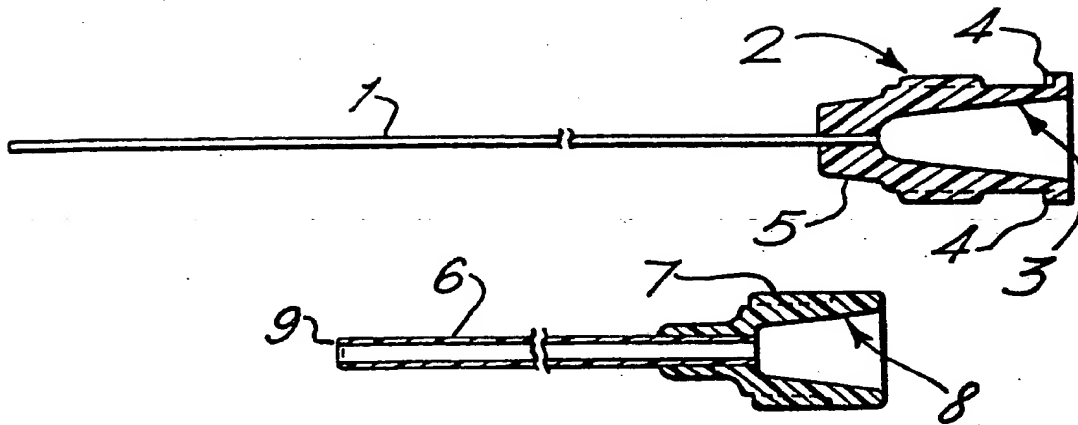


FIG. 1.

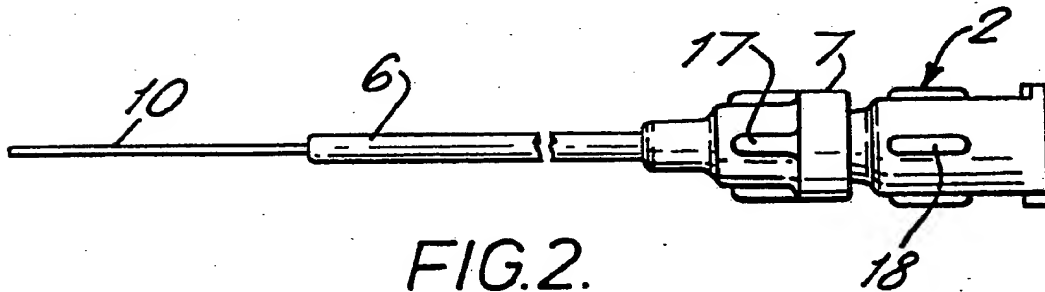


FIG. 2.

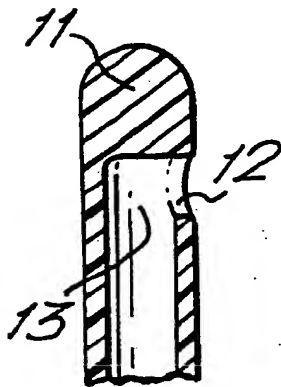


FIG. 3.

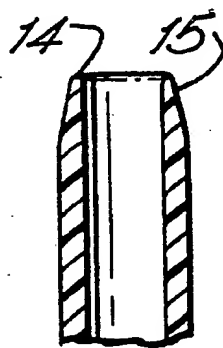


FIG. 4.



FIG. 5.

## SPECIFICATION

## Improvements in or relating to surgical devices

The present invention concerns improvements in or relating to surgical devices and more particularly concerns a device for intubation of the cervix.

Intubation of the cervix provides access to the uterus and Fallopian tubes. It is employed, for instance, when it is desired to implant a fertilised ovum, or for certain procedures involving the Fallopian tubes.

Intubation of the cervix has previously been a difficult procedure. The catheter must be fairly rigid in order to permit its introduction into the vagina and accurate placement of the catheter tip (under vision) at the external os. The external os is the entrance to the cervix and uterus. A catheter must be advanced about 6 cm beyond the external os before reaching the uterine fundus (in an adult human female). Previously, catheters have been made of polymers stiff enough to be introduced directly to the external os via the vagina, but such materials can easily damage the delicate mucous membrane of the cervical canal and uterine cavity. When the catheter is sufficiently flexible for safe introduction into the contoured cervical canal, it cannot be accurately placed at the external os.

It has also been proposed to provide a pliable catheter projecting distally through a stiffer outer sheath, which acts as a splint on the proximal portion. However it is still difficult to negotiate such a pliable end via the vagina in order to achieve accurate placement at the external os.

In one aspect our invention provides apparatus for intubation of the cervix comprising a hub connected to a flexible catheter and a sheath surrounding said catheter, said sheath being more rigid than said catheter and having an enlarged grip portion adapted to be gripped by an operator at its proximal end, said sheath being slidable from a first position in which the distal end of said catheter terminates approximately level with the distal end of said sheath to a second position in which said grip portion is abutting said hub and said catheter projects beyond the distal end of the said sheath by a distance not less than the intended depth of intubation into the cervical canal.

The invention overcomes the aforementioned problems of known devices for intubation of the cervix, by permitting the catheter tip to be placed accurately at the external os, and then advanced through the stationary sheath without causing damage to the cervical canal. The catheter can thus be selected for maximum flexibility, without compromising the ability of the operator to locate it accurately at the external os of the cervix. The sheath itself is only advanced as far as the external os.

The hub preferably comprises a cone connector such as a luer or luer lock fitting, for attachment to other apparatus, e.g. a syringe. The catheter should be made of a suitable bio-compatible, highly flexible, material, which preferably is

elastomeric. Suitable polyester-based polymers are capable of meeting these requirements.

The sheath may be made of a fluorocarbon such as PTFE or FEP polymer and may be radio-opaque. The sheath will normally have some flexibility, but will be much stiffer than the catheter.

The enlarged grip portion can be of any suitable form providing an adequate grip to the operator. For example a collar, preferably having raised ribs or wings, can be provided. Preferably the grip portion can be engaged with the hub, e.g. by means of a tapered joint such as a luer joint, or by mechanical engagement of suitable locking means. The hub and grip portions can be made of thermoplastics material such as polyethylene.

Close attention should be given to the form of the catheter tip, depending on the procedure intended to be performed. For example, for the transfer of embryos the tip of the catheter may be rounded and sealed, with a side eye. In this case the tip should be solid to the commencement of the eye so that the embryo will not be trapped in a deadspace at the tip. This solid portion may be contoured internally to direct the embryo to the exit eye. A rounded tip also allows non-traumatic negotiation of the cervical canal and avoids blockage by mucous in the cervical canal.

Alternatively the catheter may terminate either square or oblique to its length (a so-called whistle tip or flute tip), in each case the edge being suitably smoothed. Moreover the extreme end of the catheter should preferably be chamfered or tapered to facilitate its passage through the cervical canal.

The device according to the invention is useful for artificial insemination and particularly for the introduction of a fertilised ovum. The latter procedure is extremely difficult to perform successfully. Using known apparatus the success rate has been very low, whereas using a suitable apparatus according to the invention a much improved success rate has been achieved. Simultaneously other aspects of the procedure have been refined, but it is considered that the present invention contributes significantly to an improved success rate which is now possible.

The apparatus is of course applicable to human or veterinary use, by suitable adjustment of the size and proportions of the components to suit the species in question.

An embodiment of the invention will now be described by way of example only with reference to the accompanying drawings, wherein:—

Fig. 1 is an enlarged cross-sectional view of a catheter and sheath shown side by side;

Fig. 2 is a plan view of the said sheath assembled onto the said catheter; and

Figs 3, 4 and 5 are cross-sectional view, much enlarged, of three catheter tips.

Referring now to Fig. 1, catheter 1 made of an elastomeric polyester based polymer and having an external diameter of about 1 mm is bonded to the hub 2, composed of high density polyethylene. The hub 2 comprises a female luer lock cone

connector 3 having locking ears 4.

The distal end of the hub is tapered to provide a male luer connector 5.

The sheath 6 is a tube of PTFE containing a radio-opaque filler. The sheath 6 carries at its proximal end a luer connector 7 which serves as a grip portion for the operator. The internal taper 8 is dimensioned to cooperate with the taper 5 on the hub previously described. The distal end of the sheath is radiused at 9 to avoid any risk of laceration. Raised ribs 17, 18 on the grip portion 7 and hub 2 respectively facilitate handling by the surgeon.

In Figure 2, the catheter 1 has been slid through the sheath 6 and the portion 10 projects distally when the luer cones 5 and 8 are in engagement.

Turning now to Figure 3, there is shown a catheter tip having a solid rounded portion 11 and an eye 12. In Figure 4 the catheter end is square. The edge is radiused at 14 and the end is chamfered at 15 to provide a smoother passage through the cervical canal.

In Figure 5 the catheter is cut-off obliquely (as a whistle tip) and the leading edge is rounded and tapered inwardly at 16.

#### CLAIMS

1. Apparatus for intubation of the cervix comprising a hub connected to a flexible catheter and a sheath surrounding said catheter, said sheath being more rigid than said catheter and having an enlarged grip portion adapted to be gripped by an operator at its proximal end, said sheath being slidable from a first position in which the distal end of said catheter terminates approximately level with the distal end of said sheath of a second position in which said grip portion is abutting said hub and said catheter

projects beyond the distal end of said sheath by a distance not less than the intended depth of intubation into the cervical canal.

2. The apparatus of claim 1 wherein said hub comprises a cone connector suitable for attachment to a syringe.

3. The apparatus of claim 2 wherein said cone connector is a luer or luer lock connector.

4. The apparatus of any of claims 1 to 3 wherein said grip portion comprises raised ribs or wings.

5. The apparatus of any of claims 1 to 4 wherein said grip portion can be engaged with the hub by means of a tapered joint.

6. The apparatus of any of claims 1 to 5 wherein the tip of said catheter is rounded and sealed, and is provided with a side eye.

7. The apparatus any of claims 1 to 6 wherein said catheter comprises a polyester-based elastomeric material and said sheath comprises a fluorocarbon resin and is radio-opaque.

8. Apparatus for intubation of the cervix, substantially as illustrated in Figures 1 or 2 of the accompanying drawings.

9. A method for introducing a fertilised ovum which comprises (a) inserting the apparatus of any of claims 1 to 8 into the vagina, said sheath being in said first position, until the catheter tip reaches the external os; (b) advancing said catheter into the cervical canal while maintaining said sheath stationary until the tip of said catheter is adjacent the uterine fundus; and (c) expelling a fertilised ovum from said catheter tip.

10. A method for intubation of the cervix which comprises (a) inserting the apparatus of any of claims 1 to 8 into the vagina, said sheath being in said first position, until the catheter tip reaches the external os; (b) advancing said catheter into the cervical canal while maintaining said sheath stationary.